DEC 17 2013

555 North Ln, Suite 5035
Conshohocken, PA 19428

510(k) Summary

This summary of 510(k) is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The assigned 510(k) number is: K133243

Submitter: Rex Medical, L.P.
555 North Ln, Suite 5035
Conshohocken, PA 19428

Contact Person: Erich Bressler
Chief Engineer
Phone: (610) 940-0665 x107
Fax: (610) 940-1590
Email: ebressler@rexmedical.com

Date Prepared: December 13, 2013

Trade Name: Option™ ELITE Vena Cava Filter System

Common Name: Cardiovascular Intravascular Filter
(21 CFR 870.3375, Product Code DTK)

Predicate Device(s):
K081410 Option™ Vena Cava Filter System

Device Description
The Option™ ELITE Vena Cava Filter is designed for the prevention of recurrent pulmonary embolism via percutaneous delivery in the inferior vena cava (IVC).

The self-centering Option™ ELITE Filter is laser cut from nickel –titanium alloy (Nitinol) tubing. The Option™ ELITE Filter consists of shape memory Nitinol struts emanating from a central location and is designed for optimal clot capture. Retention anchors (retention hooks) are located at the proximal or caudal portion of the filter. These anchors are intended for filter fixation to the vessel wall. The Option™ ELITE Filter is intended to be used in caval diameters up to 30mm. A retrieval hook is centrally located at the cranial extremity.

The constrained Option™ ELITE Filter is flexible and expands to the internal diameter of the IVC upon deployment. The Option™ ELITE Filter imparts an outward radial force on the luminal surface of the vena cava to ensure proper positioning and stability. The Option™ ELITE Filter is designed to prevent pulmonary embolism while maintaining caval patency through central filtration.

The introduction kit is comprised of a filter housed in a filter cartridge, Catheter Sheath Introducer (5F ID), Angiographic Vessel Dilator with an open end, and a Pusher with deployment marker. The Angiographic Vessel Dilator has side holes and 2 radiopaque markers, separated by 32mm (between the

marker bands), that provide linear measurement of the inferior vena cava and assists in angiographic visualization when radiopaque contrast is delivered. The pusher advances the filter through the Catheter Sheath Introducer up to the deployment marker, and is then used to fi x the filter in place during uncovering. The location of the distal end of the Catheter Sheath Introducer can be controlled by rotating the entire device to position the Catheter Sheath Introducer in the center of the vena cava. The Filter Cartridge houses the Option™ ELITE Filter. The body of the Cartridge has text and colored arrows printed on it that identify assembly orientation, femoral is printed in green and jugular is printed in blue. The arrow of the desired access site will point into the Catheter Sheath Introducer hub. The Angiographic Vessel Dilator is designed to provide angiographic visualization and linear measurement of the vasculature when used in conjunction with the delivery of radiopaque contrast media to the vena cava.

Intended Use:
The Option™ ELITE Vena Cava Filter System is intended for the prevention of recurrent pulmonary embolism (PE) via placement in the vena cava in the following conditions:

- Pulmonary thromboembolism when anticoagulant therapy is contraindicated;
- Failure of anticoagulant therapy in thromboembolic diseases;
- Emergency treatment following massive pulmonary embolism when anticipated benefits of conventional therapy are reduced;
- Chronic, recurrent pulmonary embolism when anticoagulation therapy has failed or is contraindicated

The filter may be retrieved according to the instructions supplied in section entitled "Optional Procedure for Filter Retrieval" in patients who no longer require a filter. Retrieval of the filter can be performed only by jugular approach.

This is the same intended use as previously cleared for the Option™ Vena Cava Filter System (K081410).

Technological Characteristics:
The Option™ ELITE Vena Cava Filter System is similar with regards to materials, intended use, principles of operation and technological characteristics to the predicate device. Results of bench testing and animal studies demonstrate Option™ ELITE Vena Cava Filter System is as safe and effective as the legally marketed predicate device.

Modifications to Existing Technology:
The Option™ ELITE consists of 6 small retention hooks identical to the Option™ small retention hooks compared to the Option™ that has 3 small retention hooks and 3 large retention hooks. 3 small retention hooks provide an equal contribution to the retention force and stability as the 3 large retention hooks. Changing to a filter that has 6 small retention hooks instead of 3 small and 3 large retention hooks will allow a lower profile filter without any new issues of safety and efficacy.

The Option™ ELITE has a PTFE lined, 70cm spiral reinforced sheath made with a Pebax 6333/5533 Blend. The Option™ has a PTFE lined, 70cm braid reinforced sheath made with Pebax 7033. The inner diameter of the sheath has increased from .071" to .073". Changing the sheath from braided reinforcement to spiral reinforcement and increasing the inner diameter will facilitate the advancement of the Option vena cava filter delivery system into the IVC and advancement of the Option filter through the delivery system when encountering tortuous anatomy.

The Option™ ELITE has an alternate procedure for filter implantation where the physician can use the procedural guidewire and vessel dilator to deploy the filter instead of using the pusher to deploy the filter. This provides physicians with an additional technique to place the Option™ ELITE filter.

Non-Clinical Performance Testing:
All testing performed on the Option™ ELITE Vena Cava Filter System was derived from the risk assessment which evaluated the safety and effectiveness of the design modifications to the guidewire. Test methodology and acceptance criteria were derived from within Rex Medical and from related ISO standards for evaluation of this device.

Conclusion:
Rex Medical considers the Option™ ELITE Vena Cava Filter System to be substantially equivalent to the predicate device listed above. The conclusions are based on performance testing and similarities in indications for use, materials, technological characteristics, principle of operation and design features.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

December 17, 2013

Rex Medical
c/o Susan Goldstein-Falk
MDI Consultants, Inc.
55 Northern Blvd.
Suite 200
Great Neck, NY 11021 US

Re: K133243
Trade/Device Name: Option Elite Vena Cava Filter System
Regulation Number: 21 CFR 870.3375
Regulation Name: Cardiovascular Intravascular Filter
Regulatory Class: Class II
Product Code: DTK
Dated: September 30, 2013
Received: October 22, 2013

Dear Ms. Goldstein-Falk:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be

found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*

K133243

Device Name

Option (TM) ELITE Vena Cava Filter System

Indications for Use *(Describe)*

The Option (TM) ELITE Vena Cava Filter System is intended for the prevention of recurrent pulmonary embolism (PE) via placement in the vena cava in the following conditions:

- Pulmonary thromboembolism when anticoagulant therapy is contraindicated;
- Failure of anticoagulant therapy in thromboembolic diseases;
- Emergency treatment following massive pulmonary embolism when anticipated benefits of conventional therapy are reduced;
- Chronic, recurrent pulmonary embolism when anticoagulation therapy has failed or is contraindicated

The filter may be retrieved according to the instructions supplied in section entitled "Optional Procedure for Filter Retrieval" in patients who no longer require a filter. Retrieval of the filter can be performed only by jugular approach.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*